

REMARKS

Preliminary Remarks

Claims 89, 102-111, and 117-121 are currently pending and are under the examination. Claims 1-88 were previously canceled. Claims 89, 102, 103, 104, 105 and 106 are canceled with this response. Applicants herein amend claims 107, 110, 111, 117, 120 and 121. Claims 122-132 are newly presented. Upon entry of these amendments, claims 107-111 and 117-132 are under active consideration. Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present application.

Applicants amend claims 107 and 117 to rewrite the claims in independent form and to specify that the first portion consists “of the amino acid sequence of” residues 25-104 and 1-154 respectively.

Applicants amend claims 110, 111, 120 and 121 to provide a proper antecedent basis for each claim.

New claims 122-132 are directed to particular aspects of the invention designated Group 60.

The amendments are fully supported by the specification as filed, at least on page 2 (last paragraph) through page 3 (last paragraph), Example 6 and page 50, last paragraph. New claims 122-132 are fully supported by at least claims 55 and 68-80 as filed. Accordingly, no new matter is added by the amendments.

The specification is amended to correct typographical errors in the paragraphs beginning at the following: page 4, line 19; page 7, line 13; page 9, line 5; page 10, line 22; and page 59, line 3; and page 62, line 6. Specifically, “erythomatosis” and “erythematosis” have been corrected to “erythematosus.” No new matter is added by the amendments.

Patentability Arguments

A. The Rejections of Claims 89, 102-103, 105-106, 108 and 110-111 Under 35 U.S.C. §§ 102(a) and (e) as Being Inherently Anticipated by WO 98/39361 and U.S. Patent No. 5,969,102 Respectively, Should Be Withdrawn

At pages 3 and 5 of the Office Action, the Examiner rejected claims 89, 102-103, 105-106, 108 and 110-111 allegedly because the claims are inherently anticipated by Bram PCT

WO98/39361 ("Bram PCT") under 35 U.S.C. § 102(a) and by U.S. Patent No. 5,969,102 ("Bram US") under 35 U.S.C. § 102(e). Claims 107, 110, 111, 117, 120 and 121 are amended with this response. Claims 89 and 102-106 are canceled with this response. Applicants respectfully submit that the claims, as currently amended, are free of the prior art and in a condition for allowance.

Applicants' cancellation of claims 89, 102-103 and 105-106 render moot the rejections thereto. Accordingly, Applicants request that the rejection of these claims under 35 U.S.C. §§ 102(a) and (e) be withdrawn.

Claims 107 and 117 are drawn to fusion proteins wherein the first portion "consists of" a discrete fragment of the TACI extracellular domain. Consequently, fusion proteins wherein the first portion is the full TACI extracellular domain (i.e., residues 1-166 of SEQ ID NO:6) are excluded from the scope of the claim. *See, e.g.* MPEP § 2111.03. As neither Bram PCT nor Bram US discloses the use of a fusion protein wherein the first portion consists of amino acids 25-104 or amino acids 1-154 of the TACI extracellular domain in a method of inhibiting B lymphocyte proliferation, the rejection of claims 108 and 110-111, which depend from and incorporate every limitation of claim 107, under 35 U.S.C. §§ 102(a) and (e) may be properly withdrawn and the withdrawal is respectfully requested.

B. The Rejections of Claims 89, 102-106 and 108-111 Under 35 U.S.C. § 103 Over Bram (PCT) in View of Presta and Over Bram (US) in View of Presta Should be Withdrawn

At pages 9 and 13 of the Office action, the Examiner rejected claims 89, 102-106 and 108-111 as allegedly being obvious over alternately Bram PCT in view of U.S. Patent No. 5,739,277 (Presta) and Bram US in view of Presta.

The Examiner argues that fusion proteins of Bram PCT and Bram US are identical to those of those of applicants because the pending claims recite the open claim language "comprising" with regard to the claimed extracellular domain of TACI. As noted *supra*, Applicants have deleted claims 89 and 102-106, rendering moot any rejections directed thereto. Claims 108-111, as amended, now depend from independent claims 107 which is not rejected under 35 U.S.C. § 103(a).

As discussed *supra*, claims 107 and 117, as currently amended, are each drawn to a fusion protein, the first portion of which consists of a discrete fragment of the TACI extracellular domain. Accordingly, the claimed fusion proteins are not identical to those of Bram PCT or Bram US.

Bram PCT and Bram US did not and could not teach or suggest fusion proteins the first portion of which consists of the presently claimed discrete TACI extracellular fragments because the ligand ztnf4 was not known.

Further, Presta does nothing to render the failure of Bram PCT and Bram US. Presta deals with methods of improving recombinant protein stability by, for example, fusing the protein to an Fc fragment of an antibody.

In summary, because each of Bram PCT and Bram US fails to teach or suggest limitations of the instant claims and because Presta fails to overcome that failure, the combination cannot as a matter of law render the instant claims obvious and the rejection over Bram PCT in view Presta and the rejection over Bram US in view of Presta under 35 U.S.C. § 103(a) should be withdrawn, and the withdrawal is respectfully requested.

C. The rejection of claim 89, 102-106 and 108-111 under 35 U.S.C. § 112, first paragraph should be withdrawn.

The Examiner, at page 18 of the Office Action, rejected claims 89, 102-106 and 108-111 under 35 U.S.C. § 112, first paragraph, for allegedly failing to describe at least substantial numbers of what the Examiner characterizes as a “vast genus of soluble forms of ztnF4 receptors” and alleges that the specification does not disclose distinguishing and identifying features of a representative number of members of at least a substantial number of the members of the claimed genus.

Applicants’ cancellation of claims 89 and 102-106 render moot the rejections thereto. Accordingly, Applicants request that the rejection of these claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Applicants respectfully submit that the rejection of claims 108-111 under 35 U.S.C. 112, first paragraph is improper as these claims depend from claim 107 (not rejected) which recites a specific portion of TACI, i.e., amino acid residues 25 to 104 of SEQ ID NO:6. Nonetheless, the

phrase “ztnf4 receptor” does not appear in claim 107 as amended. Accordingly, the rejections of claims 108-111, which depend from and incorporate every limitation of claim 107, are moot.

In view of the foregoing, Applicants submit that the claims fully comply with the written description requirement of 35 U.S.C. § 112, first paragraph and thus this rejection should be withdrawn.

D. The Rejections of Claims 89, 102-111 and 117-121 under 35 U.S.C. 112, First Paragraph, Should Be Withdrawn

In their response to the action mailed May 23, 2005, Applicants: (1) amended claims 89 and 102 by inserting the phrase “a ligand binding fragment of” a soluble form of a ztnf4 receptor; (2) amended claim 107 to recite that the TACI polypeptide has an amino acid sequence consisting of “amino acid residues 25 to 104” of SEQ ID NO:6; and (3) added new claim 117 which recited that the TACI polypeptide has an amino acid sequence consisting of “amino acid residues 1 to 154 of SEQ ID NO:6.” The Examiner, at page 22 of the Office Action, rejected claims 89, 102-111 and 117-121 under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. According to the Examiner, this phrase does not appear in the specification or original claims as filed and therefore the amendments allegedly introduce new matter into the specification.

While Applicants maintain the position that the phrase “a ligand binding fragment of the” TACI extracellular domain is fully supported by the specification as filed, Applicants have deleted this phrase from the currently pending claims solely in order to expedite prosecution. Accordingly, Applicants request the withdrawal of the rejections under 35 U.S.C. § 112, first paragraph directed thereto.

The specification as filed need not provide *in haec verba* support for the language added to the claim. See, e.g., *Eiselstein v. Frank*, 52 F.2d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995).¹ Moreover, the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon

¹ Citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 at 1562, 19 USPQ2d 1111 at 1115, the court stated that the specification “need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed.”

reading the specification that the new language reflects what the specification shows has been invented. *See Eiselstein*, 52 F.3d at 1039, 34 USPQ2d at 1470.

Applicants respectfully submit that one of ordinary skill in the art would immediately discern that Applicants were in possession of the use of fusion proteins comprising a first portion consisting of the amino acid sequence of amino acid residues 1 to 154 (or amino acid residues 25 to 104) to inhibit B lymphocyte proliferation. For example, a polypeptide fusion, the first portion of which consists of amino acid residues 1-154 of SEQ ID NO:6 is an exemplary embodiment of the instant specification demonstrated to bind ztnf4 and inhibit B lymphocyte proliferation. Moreover, original claim 5 is directed to a method of inhibiting ztnf4 activity by administering a fusion protein consisting of a first portion and a second portion “wherein said first portion is selected from the group consisting of [*inter alia*] amino acid residues 1 to 154 of SEQ ID NO:6.”

Thus, applicants respectfully submit that one skilled in the art would recognize upon reading the specification that the claim language, as amended, reflects what the specification shows has been invented – a method of using a fusion protein comprising a first portion consisting of a discrete portion of TACI to inhibit B lymphocyte proliferation. Accordingly, applicants believe that claims 107 and 117 fully meet the requirement of 35 U.S.C. § 112, first paragraph, and, therefore, that the rejections should be withdrawn.

E. The Rejections of Claims 89, 102-111 and 117-121 Under 35 U.S.C. 112, Second Paragraph, Should Be Withdrawn.

At page 23 of the Office Action, the Examiner rejected claims 89, 102-111 and 117-121 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the Examiner, the use of the term “an” in the phrase “an extracellular domain of a ztnf4 receptor...” renders claim 102 vague and indefinite because the use of “an” suggests multiple ztnf4 receptor extracellular domains. Applicants have canceled claim 102. Accordingly the rejection is moot and Applicants respectfully request withdrawal thereof.

According to the Examiner, the use of the phrase “consisting amino acid residues X to Y of SEQ ID NO:6” renders claims 107 and 117 vague and indefinite because allegedly it is unclear whether the claimed domain must have the amino acid sequence of the recited portion of

SEQ ID NO:6 or merely have the same complement of amino acids present within its sequenced. Applicants have amended claims 107 and 117 to specify that the claimed domain has an amino acid sequence consisting “of the amino acid sequence of” residues X to Y of SEQ ID NO:6. Accordingly, the rejections are moot and Applicants respectfully request withdrawal thereof.


Conclusion

In view of the above amendments and remarks, applicants respectfully submit that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the (312) 595-1408. Should any additional fees be deemed necessary in connection with the filing of this document, the Commissioner is hereby authorized to deduct any such fees from Deposit Account No. 08-3038 referencing the above attorney docket number.

Respectfully submitted,

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